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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,368	04/20/2006	Frederick R. Kettinger	525.1089-PCT-US	5602

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EXAMINER	
VO, TUYEN KIM	
ART UNIT	PAPER NUMBER
2887	

MAIL DATE	DELIVERY MODE
11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,368	KETTINGER ET AL.	
	Examiner	Art Unit	
	Tuyen Kim Vo	2887	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-18, 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2008 has been entered.

Claim Objections

2. Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims 1-10 See MPEP § 608.01(n). Noted that claim 2 has been cancelled.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3-8, 11-18, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus et al. (US 6,543,692 B1, hereinafter “Nellhaus”) in view of

Sullivan et al. (US 5,992,742, hereinafter "Sullivan") and in further view of Sugihara et al. (US 7,442,387 B2).

Re claims 1, 14, 17, 25 and 26, Nellhaus, as shown in figure 10, teaches a system and method of a solid form drug (72) comprising a core portion (75) having sufficiently low friability; a readable printed or etched marking (data matrix 82) on the surface of the core, the marking providing identification/authentication of the oral dosage form. See column 4, lines 26-50.

However, Nellhaus fails to disclose or suggest the readable printed or etched marking is a covert readable printed or etched marking.

Sullivan teaches a marking code on the pill which is invisible. See column 8, lines 55-67 and column 12, lines 38-62. In addition, Sullivan further teaches a barcode is printed on a label of a pill, which has a code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed being applied thereto. See column 11, line 36 to column 12, line 43.

In view of Sullivan's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the readable printed (data matrix 82) of Nellhaus with an invisible code (covert readable printed) as taught by Sullivan so that the data cannot be seen or read by a human. Such modification would also help counter unauthorized or unintentional exchanges of pills in a container. See Sullivan: column 8, lines 55-67.

Both Nellhaus and Sullivan teach all subject matter claimed except for providing the film coating with respect to weight as now amended.

Sugihara et al. teach film coating with respect to weight, 0.3 to 2% or preferably from 0.5 to 1.5% per tablet weight. See col. 13, lines 14-35.

In view of Sugihara's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the combination of Nellhaus and Sullivan to provide the film coated with respect to the weight as taught by Sugihara since it is just a matter of selecting how much weight of the film for preferably coating on the core or tablet. Such selecting of preferably weight would not involve any inventive feature.

Re claim 3, Nellhaus further teaches the printed or etched marking is a barcode (data matrix 82). See column 4, lines 51-54.

Re claim 4, Nellhaus further teaches the barcode is a 2D data matrix barcode. See column 1, lines 13-18.

Re claim 5, Sullivan further teaches the film coat contains a colorant (the gelatin film has slightly yellow color, see Webster's II, new college dictionary, Houghton Mifflin Company, Boston, New York, Copyright © 1995, page 464). See column 11, lines 36-38.

Re claim 6, Nellhaus further teaches the marking is readable with a barcode scanner (a pen, figure 13). See column 5, line 66 to column 6, line 2.

Re claim 7, Nellhaus further teaches the marking is readable with detection equipment which does not depend upon visible light waves. See column 2, lines 29-35 and column 3, lines 15-19.

Re claims 8 and 20, Nellhaus further teaches an overt marking thereon (hybrid data matrix symbol 90, figure 12). See column 5, lines 49-57.

Re claims 11 and 18, Nellhaus further teaches the surface of the core further comprises a debossed region (icon 75, figure 10, which serves as a debossed region) into which the printed or etched marking is place. See column 4, lines 44-47.

Re claim 12, Nellhaus further teaches the debossed region has a substantially horizontal plane with respect to the center of the core. See figure 10; column 4, line 44-47.

Re claims 13, 15, 16 and 21, Nellhaus further teaches the core has an ink coating applied to a portion thereof to the marking being applied thereto. See column 3, lines 10-22.

Re claim 22, the teachings of Nellhaus as modified by Sullivan have been discussed above. In addition, Sullivan further teaches the pad printing is applied using an ingestible and pharmaceutically ink. See column 12, lines 18-28.

Re claims 23 and 24, the teachings of Nellhaus as modified by Sullivan and Sugihara have been discussed above. Nellhaus also teaches the different sizes (concentrating) of the marking such as 4x4, 5x5, etc.., see column 1, lines 25-62. Therefore, to provide the marking with the range of about 2 to about 5 ppm is obvious from the different sizes of Nellhaus since it is just a variation of sizing.

In addition, Sullivan teaches a film (a protein based film such as keratin or gelatin film) coating on the code-receiving layer. See column 11, line 36 to column 12, line 43.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus to employ the film coated on the core portion (code-receiving layer) as taught by Sullivan with the amount as suggested by Nellhaus so that to easily adhere to the pill which marking can be easily applied thereon. See column 11, lines 36-55 of Sullivan.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan and Sugihara as applied to claim 1 above, and further in view of Siegel (US 2004/0166063 A1).

Re claim 9, the teachings of Nellhaus as modified by Sullivan and Sugihara have been discussed above. However, Nellhaus as modified by Sullivan and Sugihara fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable by aroma.

Siegel teaches marking the pharmaceutical product (pills) with a covert scent profile which is detectable by aroma. See [0102] and [0103].

In view of Siegel's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Sullivan and Sugihara by providing the marking which is detectable by scent as taught by Siegel to the cover marking of Nellhau as modified by Sullivan and Sugihara in order to prevent counterfeiting of the aromas and to identify the pharmaceutical formulation/products.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan and Sugihara as applied to claims 1/8 above, and further in view of Johnson et al. (US 6,171,618 B1, hereinafter "Johnson").

Re claim 10, the teachings of Nellhaus as modified by Sullivan and Sugihara have been discussed above. However, Nellhaus as modified by Sullivan and Sugihara fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable using HPLC.

Johnson teaches a HPLC system uses to monitor or detect the dosage. See column 14, lines 3-29.

In view of Johnson's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the covert marking of Nellhaus as modified by Sullivan and Sugihara so that it can be detected by HPLC as taught by Johnson since HPLC is used to monitor or detect the chemical using UV detecting.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 3-18, and 20-26 have been considered but are moot in view of the new ground(s) of rejection.

However, Applicant traverses to the rejection by arguing that Sullivan does not teach the "core is film coated prior to said printed or etched marking being applied thereto."

However, as taught by Sullivan at column 11, lines 36-39, the code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed

being applied thereto. Moreover, film coating doesn't have to involve coating the whole body of the core/substrate and especially, it is noted that such limitation (coating the whole substrate) is not in the claim.

Regarding the weight gain on the film coated substrate, it is agreed that Nellhaus and Sullivan fails to teach such limitation. However, Sugihara et al. is introduced to provide such limitation. See explanation in section 4 above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuyen Kim Vo whose telephone number is (571)270-1657. The examiner can normally be reached on Monday - Friday, 7:30a.m. - 5:00p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven S. Paik can be reached on (571) 272-2404. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tuyen Kim Vo/
Examiner, Art Unit 2887

/Thien M. Le/
Primary Examiner, Art Unit 2887